

VPA22033/078/001

Ovisect 12.5 mg/ml Pour-On Solution for Sheep

Variation	Summary	Date
Vet - B24 a)	VNRA - Vet - B24 a) - - Vet - B24 a) - Replacement or addition of a manufacturer responsible for: batch release including batch control or testing of a sterile or non-sterile finished product	13/07/26
Vet - B21	VNRA - Vet - B21 - - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product	13/07/26
Vet - B26 c)	VNRA - Vet - B26 c) - - Vet - B26 c) - Change in the batch size (including batch size ranges) of the finished product: downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical forms or to non-sterile liquid based pharmaceutical form	13/07/26
Vet - F.II.b.1 c)	VRA-R - Vet - F.II.b.1 c) - - Vet - F.II.b.1 c) - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	13/07/26
Vet - B20	VNRA - Vet - B20 - - Vet - B20 - Replacement or addition of a primary packaging site of a non-sterile finished product	03/07/26
Vet - C1	VNRA - Vet - C1 - - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	09/02/26
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	09/02/26
Vet - F.II.b.5 z)	VRA-R - Vet - F.II.b.5 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.5 z) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	19/12/23
Vet - B3 k)	VNRA - Vet - B3 k) - k) Deletion of a non-significant in-process test (finished product manufacture) - B3 k) Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	13/12/23
Vet - B22	VNRA - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product - B22 Changes to the quality part of the dossier: Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	29/11/22
Vet - B35 a)	VNRA - Vet - B35 a) - a) Tightening of specification limits - B35	30/03/22

	a) Changes to the quality part of the dossier: Change in the specification parameters or limits of the immediate packaging of the finished product: — tightening of specification limits	
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